REMARKS

Applicants respectfully request review and reconsideration of the Office Action mailed June 5, 2007 (hereinafter Office Action), in view of the remarks and amendments contained herein. At the time of the Office Action, claims 20-38 were pending. The Office Action rejected all of the claims under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a). The rejections and response thereto are set forth fully below.

By this Amendment, claims 20, 22, and 30 are amended, claims 21 and 31 are canceled, and claims 39 and 40 are added. No new matter is added. As the total number of pending claims does not exceed twenty (20), no additional claim fees are believed to be due.

Amendments to the Specification

An Amendment to the title has been made in order to better identify the invention.

Amendments to the Claims

By this Amendment claims 20 and 30 are amended to clarify that the cut surface is produced inside the crystalline eye lens and the that controller is designed in such a way that each of the laser pulses has a pulse energy in the range from 1 picojoules (pJ) to 1 microjoules (mJ). Support for the phrase "crystalline eye lens" can be derived from the fact that the eye lens is also known as the *crystalline lens*. The energy range is incorporated from claims 21 and 31, which are deleted by this Amendment. No new matter is added.

New claims 39 and 40 recite a controller and method, respectively, wherein the cut surface exhibits low roughness and good smoothness to result in enhanced elasticity of the crystalline eye lens. Support for these claims can be found throughout the specification, including paragraph [0019].

Claim Rejections under 35 U.S.C. §102(b)/103(a)

Claims 20-38 were rejected as being anticipated by or, in the alternative under 35 U.S.C. §103(a), as being obvious over U.S. Patent Application No. 6,099,522, issued to Knopp *et al.* (hereinafter "Knopp"). The Office Action asserts that:

> Knopp et al., disclose a surgical laser system comprising a surgical laser controller adapted to control the laser to produce a cut surface inside an eye lens using multiple laser pulses. Furthermore, the controller of Knopp et al. is capable to provide the recited functions as claimed.

Applicants note that this rejection is limited to the controller claims (20-29) and does not address the method claims (30-38). Accordingly, Applicants respectfully request that the Examiner consider the features of both the controller claims and the methods claims.

Prior to reviewing the cited reference, Applicants wish to review the subject matter of the claims and provide some background concerning the invention. Amended claim 30 is drawn to:

> 30. (Currently amended) A method for the treatment of an eye lens, wherein a cut surface is produced inside the crystalline eye lens using multiple laser pulses, wherein the pulse energy of each of the laser pulses is limited to a range from 1pJ to 1 µJ.

The claimed method and device are useful for the treatment of presbyopia, which results as the elasticity of the lens is lost due to the natural aging process. The claimed method requires creating cut surfaces in the crystalline eye lens using multiple laser pulses having a pulse energy in the range of 1 picojoules (pJ) to 1 microjoules (mJ).

It is known that the refractive properties of the eye are mainly controlled by the cornea and the lens. The healing properties of the cornea and the lens are different and it is known that the cornea exhibits better healing and reduction or elimination of scar formation. Alterations inside the crystalline lens usually result in the formation of a cataract. This is one reason why most refractive surgical treatments (such as those focused on by Knopp) are directed to treatment of the cornea.

That said, certain pathologies of the eye cannot be satisfactory treated by refractive surgery of the cornea. This is because refractive treatment of the cornea only allows constant refractive changes to a certain amount. Presbyopia is an example of a disease where an alteration of the refractive power for focusing near and far objects (=accommodation) is substantially reduced or impossible due to the loss of its elasticity associated with aging. One of the main innovative aspects of the invention is to generate gliding planes (the smooth sides of the cut surfaces) into the crystalline lens in order to increase its elasticity and as a consequence to treat presbyopia.

It is important to understand that laser correction of pathologies of the eye, such a corneal refractive surgery, generally seek to provide change the refractive properties of the eye that are static. In contrast to this general approach, the subject matter of the claims deals with laser surgery to modify the lens in a manner that imparts elasticity to the lens which has be lost as a result of aging. As noted in paragraph [0002], this enables the ciliary muscles and capsule sack to accommodate the lens dynamically for viewing of objects close to the eye.

Turning now to the cited reference. Knopp discloses a method, apparatus and system for template controlled, precision laser interventions in ophthalmic surgery and industrial micromachining. The Knopp disclosure focuses on corneal refractive surgery where a laser is used to permanently reshape the curvature (refractivity) of the cornea.

Knopp focuses primarily on the treatment of specific pathologies of the human eye by corneal refractive surgery, *i.e.* a treatment of the cornea using a laser which produces internal lesions in the cornea to change its refractive properties. A number of passages in Knopp indicate this focus, including, but not limited to, column 1, lines 54-58, column 2, lines 48, 49, column 3, lines 8, 9, column 4, lines 9-23 and lines 41-51, further column 18, lines 9-14 and lines 26-28, finally claims 17 and 28.

It is noteworthy that Knopp's disclosure is drawn to the general the treatment of tissue within the human eye and in this context Knopp mentions:

- ✓ a treatment of the lens nucleus in column 18, line 20,
- ✓ the monitoring of movements of the lens in column 35, line 28, the determination of the topographical shape of the ocular lens in claim 18, and
- ✓ the focusing of the laser beam into the lens of the eye in claim 36 and claim 43.

Quite simply, Knopp does not provide any disclosure or suggestion regarding how such a laser could be used to prevent or treat presbyopia. In fact, while the terms "cornea" and "corneal" appear in the Knopp specification a combined ninety-nine (99) times, presbyopia appears once. The lone mention of presbyopia is in claim 36, which provides no information regarding how such a laser could be used to treat or prevent presbyopia. Knopp does not disclose or suggest the energy levels or pulse durations for treatment of presbyopia as set forth in the pending claims. furthermore, Knopp does not disclose or suggest the use of cut surfaces to impart elasticity to any eye tissue (the lens in particular), or the method of spatially separating

successive laser pulses from one another. Thus, it simply cannot be said that Knopp discloses or suggests the methods of the claimed invention.

In fact, the parameters of the laser device described in the method of Knopp would produce serious damage to an eye lens and would prevent a successful healing process following such surgical laser treatment. Thus, Knopp merely mentions the possibility that laser treatment may be used for preventing (not treating) presbyopia without demonstrating that this will result in an actual improvement of the function of the eye or even a healing of the pathology and without disclosing the parameters required for such treatment of the crystalline lens to ensure a positive outcome of the surgical treatment and a removal of a pathologic situation. Furthermore, permanently reshaping the curvature of the lens, the technique used in corneal refractive surgery and disclosed by Knopp, would not produce a cut plane (claims 20 & 30) or impart elasticity to the crystalline lens (claims 38 & 39) or correct presbyopia.

As noted above, the pulse energy in the claims is far smaller than the pulse energy disclosed by Knopp. The pulse energy according to the invention is 1pJ to 1μJ in contrast to the prior art, *e.g.* Knopp, proposing "less than 2mJ." The skilled person, even when considering that Knopp discloses to go below 2mJ, would never reduce the pulse energy for more than one order of magnitude or even two such orders. The main reason for this is that the skilled person will expect that no significant refractive changes would occur when the pulse energy is reduced to the values set forth in the claims. Moreover, the pulses used in the invention have a duration of 1 fs to 800 fs [a nanosecond is equal to 1,000,000 femtoseconds (fs)] whereas the pulse duration in the Knopp-reference is in the order of nanoseconds. Thus, the energy transferred by pulses of the claims is substantially less than that disclosed by Knopp.

It should also be noted that Knopp does not correlate any particular pulse energy rates to a particular tissue to be treated. Rather, Knopp generally discloses some information about a pulse energy rate of less than 2mJ and generally addresses the treatment of the cornea, making passing mention that treatment of the lens is also a possibility in a few passages. By this, Knopp completely fails to disclose the important combination of treating the lens and significantly reducing the pulse energy in this context. However, the combination of these two features are important aspects of the invention.

Another important distinction from the Knopp disclosure is that the subject matter of the claimed invention utilizes a method and mechanism that is completely different from Knopp. Whereas Knopp deals with permanently altering the geometry (optical properties) of the cornea using laser pulses to ablate tissue or induce residual stresses due to local coagulation, the method of the current claims involves ***producing a cutting plane inside a crystalline lens in order to improve the elasticity of the lens.*** In other words, the method according to the claims provides one or more gliding surfaces inside the crystalline lens to reproduce the elasticity lost due to aging and, thereby facilitate the accommodation process, *see* Specification, page 4, last paragraph.

Clearly, the Knopp reference does not contain anything that discloses or suggests this approach to impart elasticity to a crystalline lens that has lost its natural elasticity due to the aging process. In addition, applying laser pulses with the duration and pulse energy disclosed in Knopp to the crystalline eye lens would result in a cataract if not immediate destruction of the lens. The cut plane is disclosed in claims 20 & 30 and the imparting of elasticity to the crystalline eye lens in found in claims 38 & 39.

The invention provides a control device, a laser, and a method for successful treatment of existing presbyopia by treating the crystalline lens of the eye. While Knopp claims a method of preventing presbyopia, *see* Knopp, claim 36. Knopp completely fails to disclose any enabling information about how the device disclosed therein could be used to prevent presbyopia. Clearly, in addition to not disclosing or suggesting the subject matter of the claims, Knopp does not provide any form of enabling disclosure for treating presbyopia by laser treating the lens in such a way that elasticity is imparted to the crystalline eye lens.

As set forth in the claims, a controller for a surgical laser adapted to produce a cut surface inside a crystalline lens is provided as is a method for the treatment of a crystalline lens. An important aspect of the invention is the limitation of the pulse energy to a range from 1pJ to 1μJ. The Applicants has invested considerable theoretical and experimental research work to identify this parameter and this range as important. It must be noted that, in general, a high pulse energy is desirable to effect a significant refractive change by the treatment. Thus, in particular when treating diseases like presbyopia which require a softening of the crystalline lens to increase its elasticity, the general approach of the skilled person has been to increase the pulse energy in

order to treat the disease. This teaches away from the claimed invention where the pulse energy is decreased significantly, thus effecting only a minor local change in the tissue and creating cut surfaces with low roughness and good smoothness that provide the elasticity of the described in the claims.

An important and surprising effect observed by the Applicants during their research is that the healing of presbyopia after laser treatment of the lens is significantly better when conducting the treatment with a high number of pulses which are positioned very close together but each pulse having a pulse energy in the range of 1pJ to 1μJ, when compared to the treatment with a smaller number of laser pulses but each laser pulse having a pulse energy of 2mJ or close below this number as proposed in Knopp (see e.g. claim 42).

Applicants have also discovered that results are improved where the controller is programmed to use a pattern set out such that two successive pulses are produced at a distance from one another in such a way that the faults produced by the laser pulses in the eye lens do not touch or overlap one another, *see* Specification, paragraphs [0021] & [0023], and Claim 36. This prevents excess scar tissue and is not disclosed or suggested by the Knopp reference. In fact it is contrary to the Knopp disclosure, which suggests that pulses should be adjacent to one another.

New Claims and Dependent Claims

New claims 39 and 40 recite a controller and method, respectively, wherein the cut surface produced exhibits low roughness and good smoothness to result in enhanced elasticity of the crystalline eye lens. As noted above, corneal refractive surgery is used to permanently change the refractive properties of the cornea. In contrast, the subject matter of the claims is used to create cut surfaces that impart elasticity into the lens. The modified lens can then function dynamically with the ciliary muscles and capsule sack to accommodate the lens for viewing objects as they move closer to the eye.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their

dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned Greg Lefkowitz at 561-671-3624 (direct line) if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

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